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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/480,472	06/06/95	MCDONOUGH	S 2137066

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HM31/0529

EXAMINER	
TAMM J	
PAPER NUMBER	

DATE MAILED: 1634

05/29/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/480,470Z

Applicant(s)

McDonough et al.

Examiner

Joyce Tung

Group Art Unit

1634

☒ Responsive to communication(s) filed on 12/10/96 and 3/2/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 24-42, 48-51, and 54-101 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 24-42, 48-51, and 54-101 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Response to Amendment

1. The 35 U.S.C. 112, second paragraph rejection over claims 24-42, 48-51, 55 and 56 in paragraph 2 of paper N0.8 of the Office action mailed July 10, 1996 is withdrawn in light of the amendments of the response filed 12/10/96.
2. The 35 U.S.C. 112, first paragraph rejection over claims 24-38, 49, 51 and 56 in paragraph 3 of paper N0.8 of the Office action mailed July 10, 1996 is withdrawn in light of the amendments of the response filed 12/10/96.
3. The 35 U.S.C. 103 rejection over claims 24-42 and 48-51 and 54-56 in paragraph 4-7 of paper N0.8 of the Office action mailed July 10, 1996 is withdrawn in light of the amendments of the response filed 12/10/96.
4. The 35 U.S.C. 103 rejection over claims 57-101 in paragraph 4-6 of paper N0. 17 of the Office action mailed 10/01/97 is withdrawn in light of the amendments of the response filed 3/2/98.

NEW GROUND OF REJECTION

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 24-38 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 11-12, 15, 17, 20-22, 24, 26 and 29-34 of U.S. patent no. 5,554,516. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 24-38 and 54 in the instant application discloses a composition which comprises a target nucleic acid sequence, first and second oligonucleotide comprising two members wherein one of the oligonucleotide comprises promoter-primer or each of the oligonucleotide comprises promoter-primer and the 3' end of the member is modified to block extension of the oligonucleotides, RNA dependent DNA polymerase, DNA dependent DNA polymerase, RNase H, helper oligonucleotide and DMSO. This is obvious in view of claims 1-5, 11-12, 15, 17, 20-22, 24, 26, 29-34 in the patent which recite a method and composition in which one or more promoter-primer are used and these primers are modified at 3' end to prevent nucleic acid extension and some of these primers are not modified, the method also includes helper oligonucleotides and the incubation is in presence of one or more DMSO.

Claim Rejections - 35 USC § 112

7 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 24-38, 49, 51, 54, 56-73, 79-83, 91 and 94-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a. Claims 24-38, 49, 51, 54 and 56 are confusing because of the language “a first promoter-primer” which is not clear whether or not there is a second promoter-primer on the same oligonucleotide.
- b. Claims 57-73 are confusing because of the language “selected from the group consisting of SEQ ID NO:s 3 and 8, and ...” which is improper Markush language in claims 57, 59 and 60. The same improper Markush language is in claims 67, 69 and 70.
- c. Claims 79-83, 91 and 96-97 are confusing because of the language “said region consisting of SEQ ID NO: 8 or the ...” in claims 79, 81, 91, 96 and 98. It is suggested that the claims be amended to “selected from the group consisting of ... and ...”.

NEW GROUND OF REJECTION NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 24-38, 49, 51, 54 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-38, 49, 51, 54 and 56 are confusing because of the language "at least two members" and "in common". It cannot be determined what is encompassed.

Allowable Subject Matter

11. Claims 39-42, 48, 50, 55-56 and 100-101 are free of the prior art.

12. Claims 24-38, 54 and 57-99 are free of the prior art, but are rejected for other reasons.

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 6:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Joyce Tung

May 21, 1998

KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1634/600

5/26/98

Kenneth R. Horlick, Ph.D.